

IN THE SPECIFICATION:

On Page 1, line 1, please cancel the title and replace it with the following title:

‘LABELLED HUMAN Fc EPSILON RECEPTOR ALPHA CHAIN PROTEIN’

On page 6 of the specification, please replace the paragraph spanning lines 8-17 with the following paragraph:

‘One embodiment of the present invention is a method to detect a non-human IgE using an isolated human Fc_εR molecule. It is to be noted that the term "a" entity or "an" entity refers to one or more of that entity; for example, a protein refers to one or more of that proteins or at least one of that protein. As such, the terms "a" (or "an"), "one or more" and "at least one" can be used interchangeably herein. It is also to be noted that the terms "comprising", "including", and "having" can be used interchangeably. ~~It is also to be noted that the terms "comprising", "including", and "having" can be used interchangeably.~~ Furthermore, a compound "selected from the group consisting of" refers to one or more of the compounds in the list that follows, including mixtures (i.e., combinations) of two or more of the compounds.’

On page 10 of the specification, please replace the paragraph spanning lines 15-23 with the following paragraph:

‘Preferably, a recombinant cell is transfected with a recombinant molecule of the present invention ~~is a molecule~~ that can include at least one of any nucleic acid molecule heretofore described operatively linked to at least one of any transcription control sequence capable of effectively regulating expression of the nucleic acid molecule(s) in the cell to be transformed, examples of which are disclosed herein. A particularly preferred recombinant molecule includes pVL-nhFc_εRα₆₁₂. Details regarding the production of Fc_εR molecule nucleic acid molecule-containing recombinant molecules are disclosed herein. Particularly preferred recombinant cell of the present invention includes *Trichoplusia ni*-pVL-nhFc_εRα₆₁₂.’

Please replace the paragraphs spanning page 12, lines 7-23, through page 14, lines 1-5, of the specification with the following paragraph:

"In addition, a Fc_εR formulation of the present invention can include not only a Fc_εR but also one or more additional antigens or antibodies useful in detecting IgE. As used herein, an antigen refers to any molecule capable of being selectively bound by an antibody. As used herein, specific binding of a first molecule to a second molecule refers to the ability of the first molecule to preferentially bind (e.g., having higher affinity higher avidity) to the second molecule when compared to the ability of a first molecule to bind to a third molecule. The first molecule need not necessarily be the natural ligand of the second molecule. Examples of such antibodies include, but are not limited to, antibodies that bind selectively to the constant region of an IgE heavy (i.e., anti-IgE isotype antibody) or antibodies that bind selectively to an IgE having a specific antigen specificity (i.e., anti-IgE idiotype antibody). Examples of such antigens include any antigen known to induce the production of IgE. Preferred antigens include allergens and parasite antigens. Allergens of the present invention are preferably derived from fungi, trees, weeds, shrubs, grasses, wheat, corn, soybeans, rice, eggs, milk, cheese, bovines (or cattle), poultry, swine, sheep, yeast, fleas, flies, mosquitoes, mites, midges, biting gnats, lice, bees, wasps, ants, true bugs or ticks. A suitable flea allergen includes an allergen derived from a flea, in particular flea saliva antigen. A preferred flea allergen includes a flea saliva antigen. Preferred flea saliva antigens include antigens such as those disclosed in PCT Patent Publication No. WO 96/11271, published April 18, 1996, by Frank et al. (this publication is incorporated by reference herein in its entirety), with flea saliva products and flea saliva proteins being particularly preferred. According to the present invention, a flea saliva protein includes a protein produced by recombinant DNA methods, as well as proteins isolated by other methods disclosed in PCT Patent Publication No. WO 96/11271.

Preferred general allergens include those derived from grass, Meadow Fescue, Curly Dock, plantain, Mexican Fire bush, Lamb's Quarters, pigweed, ragweed, sage, elm, cocklebur, Box Elder, walnut, cottonwood, ash, birch, cedar, oak, mulberry, cockroach,

Dermataphagoides, *Alternaria*, *Aspergillus*, *Cladosporium*, *Fusarium*, *Helminthosporium*, *Mucor*, *Penicillium*, *Pullularia*, *Rhizopus* and/or *Tricophyton*. More preferred general allergens include those derived from Johnson Grass, Kentucky Blue Grass, Meadow Fescue, Orchard Grass, Perennial Rye Grass, Redtop Grass, Timothy Grass, Bermuda Grass, Brome Grass, Curly Dock, English Plantain, Mexican Fire bush, Lamb's Quarters, Rough Pigweed Short Ragweed, Wormwood Sage, American Elm, Common Cocklebur, Box Elder, Black Walnut, Eastern Cottonwood, Green Ash, River Birch, Red Cedar, Red Oak, Red Mulberry, Cockroach, *Dermataphagoides farinae*, *Alternaria alternata*, *Aspergillus fumigatus*, *Cladosporium herbarum*, *Fusarium vasinfectum*, *Helminthosporium sativum*, *Mucor recemosus*, *Penicillium notatum*, *Pullularia pullulans*, *Rhizopus nigricans* and/or *Tricophyton* spp. Preferred parasite antigens include, but are not limited to, helminth antigens, in particular heartworm antigens, such as Di33 (described in U.S. Patent Application Serial No. ~~08/715,628~~ 6,391,569, filed September 18, 1996, ~~to~~ by Grieve et al.). The term "derived from" refers to a natural allergen of such plants or organisms (i.e., an allergen directly isolated from such plants or organisms), as well as, non-natural allergens of such plants or organisms that possess at least one epitope capable of eliciting an immune response against an allergen (e.g., produced using recombinant DNA technology or by chemical synthesis)."

On page 36 of the specification, please replace the paragraph spanning lines 1-3 with the following paragraph:

"The results shown in Fig. 1 indicate that the alpha chain of human FcεRI detects the presence of canine IgE (~~closed circles~~ squares) in a solid phase assay in a similar manner as the control antibody that binds specifically to canine IgE (D9; ~~open circles~~)."

On page 38 of the specification, please replace the paragraph spanning lines 11-17 with the following paragraph:

"The results shown in Fig. 3 indicate that canine IgE from a variety of dog sera are detected using the alpha chain of human FcεR in a manner similar to

using an antibody that binds specifically to canine IgE. The absence of detectable amounts of IgE in the heat treated sample (Sample 7) indicates that the antibody detected by PhFc_εRα₁₇₂-BIOT is IgE. In addition, the results indicate that PhFc_εRα₁₇₂-BIOT is an effective reagent for detecting IgE that binds to allergen Kentucky Blue Grass, Samples 5 and 6), as well as a parasite antigen (*D. ~~Immitis~~ immitis*, Sample 2).”

Please replace the paragraph spanning page 39, lines 18-22, through page 40, lines 1-14 with the following paragraph:

‘Multiple wells of an Immulon II microtiter plate were coated with about 100 µl/well of about 1 µg/ml CMI anti-canine IgE antibody #6 (available from Custom Monoclonals International) in CBC buffer. The plate was incubated overnight at 4⁰C. The plate was blocked and washed as described in Example 4. About 100 µl/well of different samples of IgE-containing fluids in PBSBT were added to multiple wells coated with the anti-canine IgE antibody. The samples included: (1) 100 µg/ml of canine IgE purified from the heterohybridoma described in Example 4; (2) a 1:10 dilution of a pool of sera from dogs known to be allergic to flea saliva, (3) a 1:10 dilution of the same sera pool as in (2) but heat inactivated; (4) a 1:10 dilution of serum from a dog known to have clinical flea allergy dermatitis (dog CPO2); (5) a 1:10 dilution of heat inactivated CPO2 serum; (6) a 1:10 dilution of serum from a heartworm-infected dog (dog 417); (7) a 1:10 dilution of heat inactivated 417 serum; (8) a 1:10 dilution of a pool of sera from heartworm-infected dogs; (9) ~~a 1:10 dilution of the same sera pool as in (8) but heat inactivated; and (10)~~ a pool of sera from dogs raised in a barrier facility. Each sample was diluted in PBSBT. The plate was incubated for 1 hour at room temperature and then washed four times with PBST. About 100 µl/well of a 1:4000 dilution of 40 µg/ml PhFc_εRα₁₇₂-BIOT (described in Example 3) in PBSBT was added. The plate was incubated for 1 hour at room temperature. The plate was then washed, contacted with about 0.25 ug/ml streptavidin-conjugated

to horseradish peroxidase, washed again, and the presence of streptavidin bound to the plate was detected using the method described in Example 4.”

Please replace the paragraph spanning page 41, lines 13-22, through page 42, lines 1-7 with the following paragraph:

“Multiple wells of an Immulon II microtiter plate were coated with about 100 μ l/well of about 10 μ g/ml Di33 protein (described in U.S. Patent Application Serial No. 08/715,628, *ibid.*) or 10 μ g/ml crude homogenate of heartworm, both in CBC buffer. Crude homogenate of heartworm is the ~~clarified~~ clarified supernatant of adult heartworms homogenized in PBS. The plate was incubated overnight at 4⁰C. The plate was blocked and washed as described in Example 4. Serum samples from 2 heartworm infected cats were then added to Di33-coated wells and to heartworm antigen-coated wells. About 100 μ l/well of a 1:10 dilution in PBSBT of sera from heartworm-infected cat # AXH3 or from cat #MGC2 were added to the plate. Negative control samples consisting of serum from pre-infection bleeds of cat #AXH3 and cat# MGC2 were also added to the plate at a dilution of 1:10 in PBSBT. A positive control sample consisting of a pool of sera from heartworm-infected dogs was also added to the plate at a dilution of 1:10 in PBSBT. The plate was incubated for 1 hour at room temperature and then washed four times with PBST. About 100 μ l/well of a 1:4000 dilution of 40 μ g/ml PhFc_εRα₁₇₂-BIOT (described in Example 3) in PBSBT was added. The plate was incubated for 1 hour at room temperature. The plate was then washed, contacted with 1:4000 dilution of a 0.5 mg/ml solution of streptavidin-conjugated to horseradish peroxidase, washed again, and the presence of streptavidin bound to the plate was detected using the method described in Example 4.”

On page 45 of the specification, please replace the paragraph spanning lines 1-10 with the following paragraph:

‘Following the incubation, the plates were washed 4 times with PBST. About 5 µg of a murine IgG monoclonal antibody ~~ant~~ anti-canine IgE antibody (i.e., Custom Monoclonal Antibody #71; available from Custom Monoclonal International) in 100 µl of EMEM-FBS was added to each well. The plates were incubated for about 30 minutes at 37°C. Following the incubation, the plates were washed 4 times with PBST. About 100 ng of horseradish peroxidase labelled donkey anti-murine IgG (available from Jackson Laboratories, Westgrove, PA) in 100 µl of EMEM-FBS was added to each well, and the plates were incubated for about 30 minutes at room temperature. Following the incubation, the plates were washed 4 times with PBST. The presence of anti-murine IgG bound to the plates thereby indicating the ability of RBL-hFc_εR cells to bind to canine IgE was detected using the method described in Example 4.’